APR 1 3 2006

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052457.

Trade/proprietary name: PICSI™ Sperm Selection Device

Common or usual name: Assisted Reproduction Media,
Assisted Reproduction Labware

Classification: Assisted Reproduction Media, CFR 884.6180, Class II, Procode 85 MQL;
Assisted Reproduction Labware, CFR 884.6160, Class II, Procode 85 MQK

PICSI is substantially equivalent to Sperm Catch™ Assisted Reproduction Media, (510(k) K011607, decision date: 8/10/2001) and to FALCON® IVF Round Dish, (510(k) K991253, decision date 5/5/1999).

Description: The PICSI™ Sperm Selection Device is a sterile, plastic culture dish with three microdots of hyaluronan hydrogel attached to the dish and three locating lines embossed on the bottom exterior of the dish to aid the operator to find the microdots. Mature human sperm attach themselves to hyaluronan through specific receptors on the sperm plasma membrane. At temperatures from 18-28° C, mature sperm attach themselves firmly to the hyaluronan microdot and no longer exhibit progressive movement, although their tails beat and they are capable of motility. Such sperm are easily selected and removed from the hyaluronan by micropipet for intracytoplasmic sperm injection (ICSI).

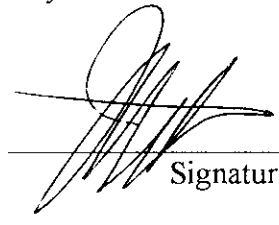
Intended Use: PICSI is intended for the selection of mature sperm for ICSI.

Technological Characteristics Compared to Sperm Catch and to FALCON IVF dish:

Factor/attribute	PICSI dish	Sperm Catch	FALCON dish
Method of facilitating sperm selection and capture by micropipette	Stops progressive movement	Slows progressive movement	N/A
Active Ingredient	Hyaluronan (hydrogel attached to Petri dish)	Hyaluronan (solution)	N/A
Sperm fraction subject	Mature motile	Total motile	N/A

to selection	fraction	fraction	
Useful Operating Temperature	18-28° C	30-37° C	0-37°C
Minimum time for set up and selection of sperm	15 min	10 min	N/A
Storage conditions	Dry, room temperature	(?) Refrigerated	(?) Dry, room temperature
Shelf Life	1 y (anticipated to be extended as aging studies are completed)	Unknown	Unknown
Sterility	Radiation sterilized	Filtration sterilized	Radiation sterilized
Endotoxin	<1 EU/device	<1 EU/mL	< 20 EU/device
Biocompatibility	Compatible (1-cell Mouse Embryo Assay, ≥75% conversion in 96 h)	Compatible (> 24 h survival in human sperm survival assay)	Compatible (2-cell Mouse Embryo Assay, ≥ 70% conversion in 72 h)

Performance: In a clinical trial involving side-by-side fertilization of oocytes by ICSI, using sperm selected on PICSI and in Sperm Catch, the fertilization rates, quality of the resulting embryos and the disposition of embryos in the PICSI and the Sperm Catch groups were compared. No statistically significant differences were found in fertilization rates, the average number of cells in the 3-day embryos, the number of 3-day embryos with 8 or more cells, the morphological characterization of the 3-, 5- and 6-day embryos and the disposition (outcomes) of the 3- and 6-day embryos.



Signature

James B. Johnston

22 February 2006

Date

K 052457

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 13 2006

James B. Johnston, Ph.D.
Principal Investigator
BIOCOAT Incorporated
211 Witmer Road
HORSHAM PA 19044

Re: K052457
Trade/Device Name: PICSI™ Sperm Selection Device
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted reproduction labware
Product Code: MQK
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Product Code: MQL
Regulatory Class: II
Dated: February 24, 2006
Received: February 27, 2006

Dear Dr. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052457

Device Name: PICSI Sperm Selection Device

Indications For Use: In the treatment of infertile couples by ICSI, PICSI is indicated for the selection of mature sperm for injection.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052457